EDITED TRANSCRIPT

MYOV – Myovant Sciences Ltd. and Pfizer Inc. Receive FDA Approval for MYFEMBREE®

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OVERVIEW:
Company discusses FDA approval of MYFEMBREE

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PRESENTATION

Operator

Good day, everyone, and welcome to Myovant Sciences MYFEMBREE FDA Approval Conference Call. Today's call is being recorded.

At this time, I would like to turn the call over to Ryan Crowe, Vice President of Investor Relations at Myovant. Please go ahead.

Ryan Crowe, Myovant Sciences Ltd. - Vice President of Investor Relations

Thank you, operator. Good morning, and thank you for joining us today to discuss the FDA approval of MYFEMBREE for the management of heavy menstrual bleeding associated with uterine fibroids in premenopausal women. Our press release as well as the slides that will be presented today are available on our Investor Relations website, investors.myovant.com.

Joining me for today's call are Dave Marek, Myovant's Chief Executive Officer; Frank Karbe, President and Chief Financial Officer; Lauren Merendino, Chief Commercial Officer; and Dr. Juan Camilo Arjona, Chief Medical Officer.

During the course of this conference call, we'll be making forward-looking statements. These include plans and expectations with respect to our products, product candidates, strategies, opportunities and financials, all of which involve certain assumptions of risks and uncertainties that are beyond our control and could cause actual results to differ materially from these statements. A discussion of these risks can be found in our SEC disclosure documents. In addition, Myovant does not undertake any obligation to update any forward-looking statements made during this call.

With that, I'll turn the call over to Dave Marek, Myovant's Chief Executive Officer. Dave?

David C. Marek, Myovant Sciences Ltd. - Principal Executive Officer & Director

Thank you, Ryan, and good morning, everyone. I'm very proud to announce the FDA approval of relugolix combination tablet, now called MYFEMBREE, the first and only once-daily oral treatment for the management of heavy menstrual bleeding associated with uterine fibroids in premenopausal women.

This approval represents a significant milestone in expanding the treatment options as MYFEMBREE has a differentiated clinical profile that we believe has the potential to become the new standard of care treatment for women with uterine fibroids. We and our partner, Pfizer, are very excited and motivated by the opportunity to improve the lives of the millions of women in the U.S. with symptomatic uterine fibroids, and we look forward to providing this new treatment option in the coming weeks.

Uterine fibroids is a highly debilitating disease that can negatively affect women during their most productive years. Uterine fibroids are noncancerous tumors that had developed in or on the muscular walls of the uterus and are among the most common reproductive tract tumors in women. Although uterine fibroids are benign tumors, they can cause debilitating systems such as heavy menstrual bleeding frequently associated in anemia and fatigue, pelvic pain, urinary and gastrointestinal symptoms, constipation, pregnancy complications, and in some cases, infertility. These symptoms can also lead to a loss of productivity at work, limitations in normal activities of daily living and social embarrassment.

In addition to being a very debilitating disease, the unmet treatment need in uterine fibroids is enormous. Of the estimated 19 million women with uterine fibroids in the U.S., approximately 5 million have sought treatment for symptoms from their health care provider. And when treatment is initiated, 3 million of these women are failed by their first-line treatment, leading approximately 85% of them to cycle through multiple therapies to seek relief. And even though 2 out of 3 women prefer a medical option versus surgery, approximately a quarter-million women a year in the U.S. make the difficult choice to undergo a hysterectomy as a last resort.

So why so many hysterectomies? Prescribers, primarily OB/GYNs generally struggle to treat symptoms of uterine fibroids because current treatment options are insufficient. When we asked prescribers their top priorities for a medical treatment for uterine fibroids, the answers were very consistent: first, stop or significantly reduce excessive menstrual bleeding; second, minimize any potential disruptive side effects; and then third, make it easy, easy for me and easy for my patients. And these women deserve better options, and we believe MYFEMBREE has a unique potential to address those treatment needs.

MYFEMBREE has the potential to redefine care for women with uterine fibroids because it does meet the treatment needs for this market. In the LIBERTY clinical program, more than 70% of women treated with MYFEMBREE responded to therapy, experiencing an average of 84% reduction in menstrual blood loss volume, more than 4-times better than placebo. And when looking at the tolerability profile, hot flush, a particularly bothersome side effect, occurred in less than 11% of Myovant patients, which is not meaningfully different than the approximately 7% of patients treated with placebo.

While duration of use is limited to 24 months due to risk of continued bone loss, the average decline in lumbar spine BMD at 12 months was under 1%. And then finally, Myovant achieves all of this with one small pill taken just once daily.

The simplicity of MYFEMBREE is enabled by its half-life and its elegant formulation that combines 40 milligrams of relugolix with 1 milligram of estradiol and 0.5 milligram of norethindrone acetate into a single tablet. We are confident in the MYFEMBREE clinical profile and confident in our ability to deliver MYFEMBREE to patients who can most benefit.

Our confidence has strengthened through our collaboration with Pfizer, which is critical to the successful launch of MYFEMBREE. It starts with the combined strength of our medical team to extend the reach of scientific exchange. The Pfizer sales team brings to the partnership of rich heritage in women's health, along with strong prescriber relationships. They will join the Myovant sales team in the field conducting in person interactions from day 1.

We have a well-known strength in marketing, particularly as a leader in direct-to-consumer promotion with tremendous media buying power as well as deep expertise in data analytics and insights. The Pfizer collaboration also allows us to leverage their experience with payers as we negotiate for fair and access timely and reimbursement for MYFEMBREE.

There is clearly a need for a new treatment option, and we are ready to launch MYFEMBREE together. We believe MYFEMBREE meets the needs of this underserved market, and we look forward to delivering a differentiated launch while redefining care for women with uterine fibroids.

Now let me turn the call over to Juan Camilo, who will walk us through the MYFEMBREE prescribing information and the relevant LIBERTY clinical data. Juan Camilo?

Juan Camilo Arjona Ferreira, Myovant Sciences Ltd. - Chief Medical Officer

Thank you, Dave. The approval of MYFEMBREE is certainly a proud achievement for our team and more importantly, the significant development for women with uterine fibroids.

Before I begin, I would like to take this opportunity to thank the patients, analysts, clinicians and advocacy groups all of whom played a critical role in bringing us to this milestone. We are thankful for their support, and we jointly celebrate this achievement on behalf of women with uterine fibroids.

MYFEMBREE is indicated for the management of heavy menstrual bleeding associated with uterine fibroids in premenopausal women, and it is the first and only once-daily oral treatment approved for this indication. Use of MYFEMBREE should be limited to 24 months due to the risk of continued bone loss, which may not be reversible. MYFEMBREE's coated tablet formulation has a diameter of about 8 millimeters can be taken with or without food and should be taken at around the same time each day.

Our LIBERTY clinical development program was designed to evaluate the long-term efficacy and safety of MYFEMBREE in women with uterine fibroids. LIBERTY 1 and 2 were replicate 24-week studies that evaluated women with heavy menstrual bleeding associated uterine fibroids who were randomized 1:1:1 to receive placebo, MYFEMBREE or relugolix 40-milligrams monotherapy for 12 weeks, followed by 12 weeks of MYFEMBREE. The results of LIBERTY 1 and 2 studies were published in the New England Journal of Medicine earlier this year.

The primary endpoint for the LIBERTY 1 and 2 studies with a responder rate at week 24. Various secondary endpoints, including change in menstrual blood loss, amenorrhea rate and change in hemoglobin were also evaluated at week 24.

At the conclusion of the LIBERTY 1 and 2, women have the option of enrolling into the 28-week long-term extension study, in which all women received MYFEMBREE regardless of the treatment they received in LIBERTY 1 or 2. Data from these 3 studies were for the basis for the approval of the label.

Women who completed a long-term extension and responded to treatment could enter a randomized withdrawal study for 1 additional year where we recently read out 2-year data from this study in women with uterine fibroids that has showed stable bone density beyond 1 year. We intend to submit this data to the FDA later this year for potential labeling updates.

Women with menstrual blood loss volume of less than 80 ml had at least a 50% reduction from baseline in menstrual over the last 35 days of treatment were considered responders. MYFEMBREE met the primary endpoint in both LIBERTY 1 and 2, achieving a responder rate of greater than 70% in both studies at week 24. The difference between the MYFEMBREE and placebo groups was statistically significant with a p-value of less than 0.0001 in both studies.

In women treated with MYFEMBREE, menstrual blood loss volume was reduced by more than 50% after 4 weeks and reached near maximal efficacy by week 8 with reduction in menstrual blood loss maintained up to week 24. The results in both LIBERTY 1 and 2 were consistent with the mean reduction in menstrual blood volume of 83.7% with MYFEMBREE compared to 17.2% with placebo in pool data from the 2 studies.

For context, in an independent study by Lucas and collaborators women with heavy menstrual bleeding considered a 22% reduction in menstrual volume to be meaningful to them.

Amenorrhea or having minimal to no menstrual bleeding is the most robust demonstration of efficacy regarding reduction in menstrual blood loss and is considered a desirable outcome by many women who have experienced heavy menstrual bleeding. Approximately half of women treated with MYFEMBREE achieved amenorrhea over the last 35 days of therapy compared to the less than 10% of women who received placebo. The difference between groups was statistically significant in both studies.

The greater reduction in menstrual blood volume of women who received MYFEMBREE led to improvements in hemoglobin in women with anemia at baseline. Anemia is associated with fatigue and other debilitating symptoms in many women with heavy menstrual bleeding associated with uterine fibroids. The difference between groups in both studies was also statistically significant.

The MYFEMBREE prescribing information includes a box warning. MYFEMBREE may increase the risk of thromboembolic disorders and vascular events, including pulmonary embolism, deep vein thrombosis, heart attack or stroke. Women over 35 years of age who smoke, women with uncontrolled hypertension or with other risk factors are at a greater risk for these events.

MYFEMBREE is contraindicated in several groups of women, including those at high risk for blood clots or are pregnant, with known osteoporosis, with a history of breast cancer or other hormone-sensitive malignancies, with the known hepatic disease, those who have undiagnosed abnormal uterine bleeding or those who are allergic to MYFEMBREE.

MYFEMBREE may cause a decrease in bone mineral density in some women that may not be completely reversible. Baseline and periodic BMD assessments are recommended. A complete list of warnings and precautions can be found in the MYFEMBREE prescribing information.

The most common adverse reactions reported in at least 3% women treated with MYFEMBREE and at an incidence greater than placebo during LIBERTY 1 and 2 included hot flush, hyperhydrosis and night sweats, abnormal uterine bleeding, alopecia and decreased libido. Serious adverse reactions were reported in 3.1% of women treated with MYFEMBREE compared with 2.3% of women receiving placebo. The discontinuation rate due to adverse reactions were similar across both treatment groups. The most common adverse reaction leading to discontinuation of MYFEMBREE was uterine bleeding with the onset usually reported within the first 3 months of therapy. Common adverse reactions in the LIBERTY extension study were similar to those observed in LIBERTY 1 and 2 studies.

The effect of MYFEMBREE on bone mineral density, or BMD, was assessed by dual energy x-ray absorptiometry or DXA. The least square mean percent change from baseline in lumbar spine BMD at

month 6 in the LIBERTY studies was minus-0.23% for MYFEMBREE compared to 0.18% for placebo. As you can see from the arrow bars on the chart, the 95% confidence intervals overlap.

In addition to the LIBERTY program, Myovant conducted a separate concurrent preselected observational study that enrolled 262 women with uterine fibroids who are age matched to participants on the LIBERTY studies and a natural history observational study. The women in this study who did not receive treatment for uterine fibroids underwent DXA scans at months 6 and months 12 to monitor for changes in BMD. As you can see in the graph at the top, the mean percent change from baseline in BMD at the lumbar spine at month 6 was 0 and at month 12 was minus-0.41%.

At the bottom of the slide, data from the 6- and 12-month time points of the LIBERTY clinical program are presented. At month 6, the mean percent change from baseline in BMD at the lumbar spine was minus-0.23%, at month 12 was minus-0.8%. After 1 year, a decline in lumbar spine BMD of greater than 3% was observed in 23% of women who received MYFEMBREE in the LIBERTY extension study and 17.4% of untreated women in the natural history study. A decline of greater than 8% was seen in 1% of women in each group.

We were proud of our data and the potential for MYFEMBREE to improve patient lives. I will now turn it over to Lauren to discuss MYFEMBREE launch revenues. Lauren?

Lauren Merendino, Myovant Sciences Ltd. - Chief Commercial Officer

Thank you, Juan Camilo. This is truly an exciting time for Myovant and for women with uterine fibroids. We are thrilled to launch MYFEMBREE in the United States in mid-June.

Today, I'll review some of the progress we and Pfizer have made in preparing for the MYFEMBREE launch. Our launch strategy has a comprehensive focus across providers, payers and patients with the overarching goal of ensuring a positive first experience for all customers.

With prescribers, we will position MYFEMBREE as an effective, well-tolerated and convenient option for their patients with symptomatic uterine fibroids. OB/GYNs are largely dissatisfied with current treatments, and there's an opportunity for MYFEMBREE to help many patients who need relief today.

Our goal with payers is to establish broad coverage quickly, which we believe is possible given the strong value proposition for MYFEMBREE relative to other treatment options, many of which are not indicated for the management of heavy menstrual bleeding associated with uterine fibroids. For patients, we hope to drive MYFEMBREE product awareness through various channels with the goal of activating women who are dissatisfied with their current treatment regimen for their heavy menstrual bleeding. We will also have comprehensive patient support programs and services available at launch. With this framework, we are confident that we will be able to deliver a differentiated launch and an excellent treatment experience for prescribers and patients from day 1.

We will launch MYFEMBREE with over 200 sales professionals across both companies. We recently completed the hiring of the Myovant sales force of approximately 100 sales professionals dedicated to women's health, and then they are actively preparing for our upcoming launch. On average, our team members have 16 years of industry selling experience, including 7 years in women's health, many with established relationships in their geography, helping us gain rapid access to key customers at launch. Over 90% of our representatives have been recognized for their past performance with top sales awards. This team was built specifically for the needs of this market. We sought out passionate representatives who are driven to change treatment paradigms and redefine care for women. Our collective sales team will target approximately 25,000 OB/GYNs that write the vast majority of prescriptions for uterine fibroids. Leveraging 2 sales teams allows us to increase frequency with key

customers while also extending reach to a broader group of providers. With vaccination rates high and the pandemic subsiding, many offices are re-opening to sales representatives. Both teams will be able to engage with customers face to face at launch and have the technology to engage with customers virtually if preferred. We believe that in-person detailing increases access to customers and enhances the impact of our engagement.

Our sales team will have access to a full range of promotional materials at launch, including digital and print prescriber education materials and the *New England Journal of Medicine* publication of LIBERTY 1 and 2 studies that will be provided in a reprint carrier that summarizes the results of the publication. To supplement our field-based effort, our HCP web page is up and running to support providers seeking information on MYFEMBREE.

From a coverage perspective, we anticipate that approximately 85% of patients that are prescribed MYFEMBREE will be commercially insured. The remaining 15% of patients primarily includes cash pay or patients on Medicaid plans. This heavy concentration of commercial-insured patients underscores the importance of not only broad access, but also the quality of that access. We have already held preliminary discussions with key commercial payers and believe we are well positioned to establish affordable access for patients within 1 year.

For MYFEMBREE, we will leverage a traditional retail pharmacy distribution model, unlike the specialty distribution network we are using for ORGOVYX.

Regarding price, the MYFEMBREE wholesale acquisition cost is $974.54 per 28-count bottle, at parity with the other approved oral therapy for uterine fibroids, supporting our goals of driving patient access and affordability. After a prescribing decision has been made, our patient support programs will help facilitate access to MYFEMBREE. These resources include benefits investigation, prior authorization and appeal support, starter and bridge programs, co-pay support for commercial-insured patients and patient assistance for qualified uninsured patients. Virtual reimbursement managers will work with practices to support their efforts to obtain coverage and identify support services for eligible patients.

We have heard from OB/GYNs and patients about the importance of seamless access. We believe our patient support programs will enable a positive first experience by making access to MYFEMBREE as easy as possible for patients and prescribers, which is critical for building confidence in our brand.

Driving patient awareness is also a critical part of our launch strategy. Our initial efforts will primarily include targeted investments in search, building media and advocacy relationships and our patient brochure, which you can see on the right side of this slide. Since the inception of Myovant, we've known it was important to spark a movement within the community, educate women about uterine fibroids and then empower women to talk about their uterine health and their treatment options. We will continue to build on these initiatives over time to supplement our efforts with physicians and payers.

We believe MYFEMBREE addresses the needs of both providers and patients through its differentiated clinical profile and convenient one-pill, once-a-day dosing. We are incredibly excited to be launching MYFEMBREE and bringing an important treatment option to women with uterine fibroids. Together with Pfizer, we are confident that we can deliver a launch that changes the treatment paradigm for uterine fibroids and then redefines this underserved market.

I'll now turn it over to Dave for some closing remarks.

David C. Marek, Myovant Sciences Ltd. - Principal Executive Officer & Director

Thank you, Lauren and Juan Camilo. The approval of MYFEMBREE marks Myovant's second FDA approval in under 6 months, remarkable execution driven by our employees' commitment to redefining care. I'm extremely proud of the work our teams have put forth to execute a strong ORGOVYX launch and, as Lauren described, preparing for a successful launch of MYFEMBREE. We believe MYFEMBREE can become the standard of care by delivering the profile prescribers want most within a uterine fibroids treatment, thereby unlocking the potential of this market.

In addition to continuing to execute on our launches, during the remainder of this year, we'll bring several other important milestones. We would plan to submit our U.S. regulatory filing for endometriosis later this quarter. With the positive CHMP opinion in hand, we expect the European Commission to make its decision on our uterine fibroids filing by mid calendar year. Pfizer will provide us with their decision regarding relugolix international oncology rights midyear. And our European filing for endometriosis will also be submitted in the second half of this year. Finally, we also expect to submit our randomized withdrawal study results to the FDA towards the end of the year, which will include our 2-year bone mineral density data.

With all of this success, Myovant's financial position is further strengthened by a $100 million regulatory milestone payment from Pfizer following the MYFEMBREE FDA approval. Myovant is now in a position to positively impact the lives of so many men and women as we look forward to what's ahead. Thank you for your attention, and I'll turn it over to Ryan to begin the Q&A session.

Ryan Crowe, Myovant Sciences Ltd. - Vice President of Investor Relations

Thank you, Dave. Operator, can we now please poll for questions?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Our first question will comes from the line of Phil Nadeau from Cowen.

Philip M. Nadeau, Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

Congratulations on the second approval. Very well done. Just a couple of questions from us. First, on the randomized withdrawal study, do you have any indication from the FDA whether that would be sufficient to have the treatment duration limitation removed from the label? Or does the FDA have given you any guidance on what would be necessary to have the treatment duration extended?

David C. Marek, Myovant Sciences Ltd. - Principal Executive Officer & Director

Phil, thanks for the question. I'll let Juan Camilo address that.

Juan Camilo Arjona Ferreira, Myovant Sciences Ltd. - Chief Medical Officer

Yes. At this point in time, we have not discussed the FDA, the role of the randomized withdrawal study. We are -- we just got the approval, but we're looking forward to having those discussions in the near future.

Philip M. Nadeau, Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

That's helpful. And then second, on the launch, you mentioned several times of differentiated launch. I think we, in the investment community, are all scratching our heads as to what went wrong with the AbbVie launch. Any key learnings that you've gleaned from what they've done? And maybe what you could do differently to drive uptake a bit more quickly?

David C. Marek, Myovant Sciences Ltd. - Principal Executive Officer & Director

Thank you, Phil. Lauren, will you address that?

Lauren Merendino, Myovant Sciences Ltd. - Chief Commercial Officer

Yes. So I think the difference here is that MYFEMBREE brings to the market a product that meets the 3 things that OB/GYNs want in a uterine fibroid treatment. It aligns with the fact that they're looking for efficacy, especially around the most challenging symptom, the heavy menstrual bleeding; tolerability, particularly as it relates to hot flush; and the convenience of 1 pill once a day. And so our product profile is the #1 reason we believe we'll have a differentiated launch.

The second reason is providing an optimal first experience starting day 1. So we plan to have comprehensive patient support programs in place at launch that will help physicians and patients have that positive first experience.

And then the third piece is field execution. So having 2 teams with experienced women's health sales professionals and established customer relationships is a benefit starting day 1. And then leveraging those 2 teams in order to increase frequency on our key customers and also have the broad reach across a larger swath of customers will help us to optimize getting our message to physicians quickly.

Philip M. Nadeau, Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

That's very helpful. And then last question from us, just on the prescription data. It sounds like since you're going through retail pharmacies, the data that's available for most prescription services should be accurate. Is that fair?

David C. Marek, Myovant Sciences Ltd. - Principal Executive Officer & Director

Yes. Thanks, Phil. Yes. We'll be going through the traditional retail model. So the data that you would typically follow on, that should be what you would track.

Philip M. Nadeau, Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

Perfect, congratulations again.

Operator

Our next question will come from the line of Eric Joseph from J.P. Morgan.

Hannah Temiloluwa Adeoye, JPMorgan Chase & Co, Research Division - Research Analyst

This is Hanna on for Eric. Congrats on approval. Just a few from us. First, from your discussions with physicians, what are you currently seeing in terms of product and brand awareness? And what are your expectations among providers in terms of how they incorporate Myovant into their process. Also, how important to you is direct-to-consumer in the overall marketing push? And when might we see this begin? Then I have a follow-up after that.

David C. Marek, Myovant Sciences Ltd. - Principal Executive Officer & Director

Okay. Thank you, Hannah. I'll let Lauren address those questions.

Lauren Merendino, Myovant Sciences Ltd. - Chief Commercial Officer & Director

Yes. From an awareness perspective, we're quite pleased, as you can imagine, this is a broad audience of customers. But prior to launch, we found awareness in about 1 of 3 of our customers, which is in line with other -- of what we would expect in a pre-launch setting in this marketplace. The second question?

David C. Marek, Myovant Sciences Ltd. - Principal Executive Officer & Director

I think as it relates to direct-to-consumer and the degree to which we're looking at consumer promotion.

Juan Camilo Arjona Ferreira, Myovant Sciences Ltd. - Chief Medical Officer

And when we might expect that.

Lauren Merendino, Myovant Sciences Ltd. - Chief Commercial Officer & Director

Yes. So we do have a component of our strategy that is direct-to-consumer. And that -- but we do think it's important to sequence that and, first, to have time to educate physicians and then also get payer coverage secured before we start dialing up direct-to-consumer. So we will have some initial investment in search, et cetera, but we won't really dial up our direct-to-consumer efforts until after we've had -- time to get messages out to physicians and also secure payer coverage.

David C. Marek, Myovant Sciences Ltd. - Principal Executive Officer & Director

And Hannah, I think one of the things that we think about with direct-to-consumer advertising as we kind of lean into the online media first because we find that a highly efficient means and then a very targeted means to reach consumers. And then we'll look at options to expand beyond that as time evolves. Do you have a follow-up?

Hannah Temiloluwa Adeoye, JPMorgan Chase & Co, Research Division - Research Analyst

Yes. A follow-up on that is you mentioned that one of your initial targeting strategies would be that you're looking to target patients currently dissatisfied with their treatment options that they're on right now. But a significant portion of uterine fibroids patients aren't receiving treatment. Just wondering if there are any particular subsets of patients that you might look to target that may not be looking to other available therapies, for example? Are there any patients, particularly sensitive to bone mineral loss, for whom your safety data might be a particular selling point?

David C. Marek, Myovant Sciences Ltd. - Principal Executive Officer & Director

I think you've touched on a key area, Hannah, that initially, we know that prescribers, when they look at a new therapy like MYFEMBREE, we know that they will -- and then lean into those patients that they're struggling to take care of right now. And those are mostly the treatment-experienced patients. But we also realize there's tremendous untapped potential in this marketplace. As you may have heard us say in previous calls, almost 50% of women with heavy menstrual bleeding associated with uterine fibroids have never even talked to their doctor about their condition. And so one of the strengths of our partnership with Pfizer, is there strong ability to engage patients in both branded and nonbranded means. And we think that's going to be a key opportunity for us to leverage Pfizer's strength to really activate those patients through education and encouraging them to have a discussion with their health care providers. So we do see this as a tremendous opportunity to help appropriately grow the treated patient population with uterine fibroids

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Operator

Our next question comes from the line of Mohit Bansal from Citigroup.

Mohit Bansal Citigroup Inc., Research Division - Director and Analyst

Congrats on approval. Maybe a couple of questions from my side. One on the black box warning. It seems a little bit odd given that Lupron doesn't have it. Any particular reason you could think of from (inaudible) a bit more conservative in terms of providing the label?

David C. Marek, Myovant Sciences Ltd. - Principal Executive Officer & Director

Thank you for the question, Mohit. I think that I heard most of it. It was a little soft there, but I'm going to turn it over to Juan Camilo to address the black box warning as we would see in this class.

Juan Camilo Arjona Ferreira, Myovant Sciences Ltd. - Chief Medical Officer

Yes. Thanks, Dave. Yes, Mohit, the boxed warning that we have in our label is consistent with that, you will find in all products that contain estrogen-progestin combinations. And it's related to the hormonal components of MYFEMBREE and not to the GnRH antagonist. So that's why you wouldn't find it in, for example, Lupron, which does not contain hormones.

Mohit Bansal Citigroup Inc., Research Division - Director and Analyst

Got it. Got it. Can you hear me better now?

Juan Camilo Arjona Ferreira, Myovant Sciences Ltd. - Chief Medical Officer

Yes. Yes, that's better.

Mohit Bansal Citigroup Inc., Research Division - Director and Analyst

Great. So second question, I mean, I think a little bit surprising that FDA also asked you to -- label also asked for limiting the usage for 24 months, which is -- because obviously you're using hormones. So the bone loss issue is not as big. Can you just walk us through the discussions you had with the FDA? And is there a possibility that this 24-month limitation could come off? And then the related question is, for these women, given their age at that -- when they had between uterine fibroids, do you expect -- how long do you expect these patients to realisticaly benefit in terms of if they take it for 4 years, 5 years? Because if I understand correctly, this is basically a bridge to menopause. So 24 months is probably not going to be enough? Or is it going to be enough?

David C. Marek, Myovant Sciences Ltd. - Principal Executive Officer & Director

Thank you, Mohit. I'll let Juan Camilo discuss the -- our views on treatment duration and how it relates to our label and the treatment of patients' duration

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Juan Camilo Arjona Ferreira, Myovant Sciences Ltd. - Chief Medical Officer

Yes. Let's -- I'm not going to dive into our discussions with FDA. We usually don't describe that. But I'll give you our perspective on the current label and the overall view of our development program. As you know, our program was designed, as I mentioned earlier in our prepared remarks, to demonstrate efficacy and safety over the long term. So we provided the FDA with the first year of data, and that was the FDA used to as the basis for our decisions to inform the current label. We have 2-year data that we presented recently. And we plan to discuss with FDA, as I mentioned to Phil earlier, soon and then submit that data set to them by the end of this year.

With regards to what that will do to label, that will be part of the discussion we plan to have at the FDA and their assessment of the data in the future.

David C. Marek, Myovant Sciences Ltd. - Principal Executive Officer & Director

I think the other -- yes, I think the other element regarding the duration of use for treatment for patients, recall, we do have -- we have demonstrated the randomized withdrawal study that describes what happens when patients discontinue therapy. So Juan Camilo, maybe you could address that as well. Although those data are not in the in the label and were not submitted to FDA, it could help inform how prescribers view treating patients. Juan Camilo?

Juan Camilo Arjona Ferreira, Myovant Sciences Ltd. - Chief Medical Officer

Yes. Thank you, Dave. That's a really good point. As you may recall, Mohit, in the randomized withdrawal study, we saw that in patients who have responded to treatment, after they discontinued treatment, heavy menstrual bleeding returns relatively rapidly with an average of around 6 weeks. And so therefore, the expectation is that, in practice, if that were to happen, patients will return to their bleeding status from prior to treatment. But what we also demonstrated in that study that re-initiation of therapy in those same patients led them to return to full control in the majority of those patients very, very quickly. So I think that as we discussed the data with the FDA and we present this data to the scientific community, that will help inform physicians on how to use MYFEMBREE

Operator

Our next question comes from the line of Paul Choi with Goldman Sachs.

Charlie Ferrante, Goldman Sachs Group, Inc., Research Division - Equity Analyst

This is Charlie on for Paul. Congratulations on the approval. Just a couple from us. We've heard a lot about the patient support program and sales force collaboration efforts with Pfizer regarding the ongoing launch of ORGOVYX. And I was wondering if we could just hear a little bit more about how patient support and sales force strategies with Pfizer might compare and contrast with the ongoing launch of ORGOVYX considering the different indication in patient population? And then I have a follow-up.

David C. Marek, Myovant Sciences Ltd. - Principal Executive Officer & Director

Thank you, Charlie. In short, we have 2 different efforts from sales as well as for patient support. But I'll let Lauren address that more specifically in terms of the resourcing for each of those independently.

Lauren Merendino, Myovant Sciences Ltd. - Chief Commercial Officer & Director

Yes. So first of all, just to clarify, both on the Myovant side as well as on the Pfizer side, the women's health and oncology field teams are separate. So our field collaboration with Pfizer has 2 teams working on prostate cancer and 2 teams working on women's health. So they're completely distinct. So we don't think there's any risk of competing for time and promotion. So I just want to make sure that, that was clear.

And then from a patient support program, if there are specific questions you have, I'm happy to answer them. I think as we reviewed in the slides, we have a complete suite of services available to patients,

some of which are similar to what we have supporting ORGOVYX and some that are more unique to the women, the uterine fibroid patients' needs.

Charlie Ferrante, Goldman Sachs Group, Inc., Research Division - Equity Analyst

That's very helpful color. And then my follow-up question was regarding the subset of patients that was described in the presentation that cycle through different sequences of therapies as they're looking for an effective treatment for their uterine fibroids. And I was wondering, do you think that there's a chance of any sort of carryover of current ORIAHNN patients over to MYFEMBREE? Or do you think the limitation of duration for both drugs would limit prescriptions for MYFEMBREE for prior ORIAHNN patients?

David C. Marek, Myovant Sciences Ltd. - Principal Executive Officer & Director

Thank you, Charlie. I think when we look at the marketplace, we're really looking at those patients who have our treatment experience through their first-line therapy, which is largely going to be oral contraceptives, et cetera. And that's where the both the bolus of the patients are. And then as they cycle through multiple therapies, those patients we know out there in general are largely having their needs unmet. And then so when you think about 3 million patients that have been failed by their first-line therapy, there are plenty of patients that we believe that we can address, and that's what we're hearing from providers. So tremendous market opportunity. We think that the consideration for MYFEMBREE will largely be after the first utilization of therapy.

Charlie Ferrante, Goldman Sachs Group, Inc., Research Division - Equity Analyst

Congratulations again.

Operator

And our next question comes from the line of Jason Butler from JMP Securities.

Jason Nicholas Butler, JMP Securities LLC, Research Division - MD, Director of Healthcare Research & Equity Research Analyst

Congrats on the approval. I guess just thinking about the fact that docs are somewhat familiar with the mechanism already. Can you maybe speak to how you think about gaining patient share in patients directly after oral contraceptive versus patients having to go through other mechanisms or taking share from elagolix?

David C. Marek, Myovant Sciences Ltd. - Principal Executive Officer & Director

Jason, thanks for the question. I think one of the key areas that we believe is really understanding the marketplace and helping to drive kind of empathy for patients with uterine fibroids. And then the more that providers and payers understand what these women are going through, we think that there will be more urgency to quickly get them to the most effective therapy and certainly prior to the decisions around hysterectomy. So we believe that the data that we have is compelling to want prescribers to help these patients faster. And then therefore, we hope that as they gain treatment experience that it

will motivate them to do leverage what MYFEMBREE has to offer with patients earlier in the treatment cycle.

Operator

And I'm not showing any current questions in the queue.

David C. Marek, Myovant Sciences Ltd. - Principal Executive Officer & Director

Okay. So thank you all for participating with us today. As you can see, Myovant is at a very exciting time in its evolution, from from a clinical-stage company to a clinical and commercial stage company. We're well positioned, both operationally and financially to deliver strong commercial execution and build sustainable, long-term value. So thank you all for participating, and I look forward to keeping you updated on our progress.

Operator

This concludes today's conference call. Thank you for participating. You may now disconnect.

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